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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

JUANITA M. RIVERA and ANTHONY RIVERA, W/H,)	CASE NO. 1:12-cv-07715-RMB-JS
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Plaintiffs,))
))
v.))
NEW ENGLAND COMPOUNDING PHARMACY, INC., d/b/a NEW ENGLAND COMPOUNDING CENTER,)	<u>DEFENDANT AMERIDOSE, LLC'S ANSWER AND AFFIRMATIVE DEFENSES TO PLAINTIFFS' COMPLAINT</u>
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and))
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AMERIDOSE, LLC,))
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and))
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ALAUNUS PHARMACEUTICAL, LLC,))
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and))
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SOUTH JERSEY HEALTHCARE,))
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and))
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SOUTH JERSEY REGIONAL MEDICAL CENTER,))
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and))
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NITESH BHAGAT, M.D.,))
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and))
))
JOHN DOE(S) CORPORATIONS (1-4)))

and)
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JOHN DOE(S), M.D. (1-3),)
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and)
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Defendants)
)
)

Defendant Ameridose, LLC, by and through its undersigned counsel, hereby answers Plaintiffs' Complaint as follows:

PARTIES

1. No response is required for Paragraph 1.
2. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 2.
3. The allegations in Paragraph 3 are not directed to this Defendant so no response is required. To the extent one is deemed required, Defendant denies the allegations in Paragraph 3 for lack of knowledge or information sufficient to form a belief about the truth of these allegations.
4. The allegations in Paragraph 4 are not directed to this Defendant so no response is required. To the extent one is deemed required, Defendant denies the allegations in Paragraph 4 for lack of knowledge or information sufficient to form a belief about the truth of these allegations.
5. Defendant denies that it is a corporation, but states that it is a Massachusetts Limited Liability Company with a principal place of business located at 205 Flanders Road, Westborough, MA 01581.

6. Defendant admits that it is in the business of manufacturing, compounding, marketing, and selling certain medications. Defendant denies that it manufactured, compounded, marketed, and/or sold methylprednisolone acetate (MPA).

7. The allegations in Paragraph 7 are not directed to this Defendant so no response is required. To the extent one is deemed required, Defendant denies the allegations in Paragraph 7 for lack of knowledge or information sufficient to form a belief about the truth of these allegations.

8. The allegations in Paragraph 8 are not directed to this Defendant so no response is required. To the extent one is deemed required, Defendant denies the allegations in Paragraph 8 for lack of knowledge or information sufficient to form a belief about the truth of these allegations.

9. Defendant admits that it has common ownership with Defendants NECC and Alaunus. Defendant denies the remaining allegations against it in Paragraph 9.

10. No response is required for Paragraph 10.

11. The allegations in Paragraph 11 are not directed to this Defendant so no response is required. To the extent one is deemed required, Defendant denies the allegations in Paragraph 11 for lack of knowledge or information sufficient to form a belief about the truth of these allegations.

12. The allegations in Paragraph 12 are not directed to this Defendant so no response is required. To the extent one is deemed required, Defendant denies the allegations in Paragraph 12 for lack of knowledge or information sufficient to form a belief about the truth of these allegations.

13. The allegations in Paragraph 13 are not directed to this Defendant so no response is required. To the extent one is deemed required, Defendant denies the allegations in Paragraph 13 for lack of knowledge or information sufficient to form a belief about the truth of these allegations.

14. The allegations in Paragraph 14 are not directed to this Defendant so no response is required. To the extent one is deemed required, Defendant denies the allegations in Paragraph 14 for lack of knowledge or information sufficient to form a belief about the truth of these allegations.

15. The allegations in Paragraph 15 are not directed to this Defendant so no response is required. To the extent one is deemed required, Defendant denies the allegations in Paragraph 15 for lack of knowledge or information sufficient to form a belief about the truth of these allegations.

16. The allegations in Paragraph 16 are not directed to this Defendant so no response is required. To the extent one is deemed required, Defendant denies the allegations in Paragraph 16 for lack of knowledge or information sufficient to form a belief about the truth of these allegations.

17. The allegations in Paragraph 17 are not directed to this Defendant so no response is required. To the extent one is deemed required, Defendant denies the allegations in Paragraph 17 for lack of knowledge or information sufficient to form a belief about the truth of these allegations.

18. The allegations in Paragraph 18 are not directed to this Defendant so no response is required. To the extent one is deemed required, Defendant denies the allegations in Paragraph

18 for lack of knowledge or information sufficient to form a belief about the truth of these allegations.

19. The allegations in Paragraph 19 are not directed to this Defendant so no response is required. To the extent one is deemed required, Defendant denies the allegations in Paragraph 19 for lack of knowledge or information sufficient to form a belief about the truth of these allegations.

20. The allegations in Paragraph 20 are not directed to this Defendant so no response is required. To the extent one is deemed required, Defendant denies the allegations in Paragraph 20 for lack of knowledge or information sufficient to form a belief about the truth of these allegations.

21. The allegations in Paragraph 21 are not directed to this Defendant so no response is required. To the extent one is deemed required, Defendant denies the allegations in Paragraph 21 for lack of knowledge or information sufficient to form a belief about the truth of these allegations.

22. The allegations in Paragraph 22 are not directed to this Defendant so no response is required. To the extent one is deemed required, Defendant denies the allegations in Paragraph 22 for lack of knowledge or information sufficient to form a belief about the truth of these allegations.

23. The allegations in Paragraph 23 are not directed to this Defendant so no response is required. To the extent one is deemed required, Defendant denies the allegations in Paragraph 23 for lack of knowledge or information sufficient to form a belief about the truth of these allegations.

FACTS

24. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 24.

25. Defendant denies that it manufactured and/or compounded MPA. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 25 as to the other Defendants.

26. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 26.

27. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 27.

28. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 28.

29. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 29.

30. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 30.

31. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 31.

COUNT I – VIOLATIONS OF THE PRODUCT LIABILITY ACT,
N.J. STAT. § 2A:58C-1 TO 7

32. Defendant repeats and restates the responses of the preceding paragraphs as if fully set forth herein.

33. Defendant denies that it manufactured, compounded, and/or sold MPA. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 33 as to the other Defendants.

34. Defendant denies that it manufactured, compounded, and/or sold MPA. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 34 as to the other Defendants.

35. Defendant denies that it manufactured, compounded, and/or sold MPA. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 35 as to the other Defendants.

36. Defendant denies that it manufactured, compounded, and/or sold MPA. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 36 as to the other Defendants and Plaintiff's injuries.

37. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 37.

RESPONDING TO WHEREFORE CLAUSE

Defendant denies entitlement to the relief requested in the Complaint. Defendant demands a trial by jury.

COUNT II - NEGLIGENCE

38. Defendant repeats and restates the responses of the preceding paragraphs as if fully set forth herein.

39. Defendant denies that it manufactured, compounded and/or sold MPA. Defendant is not required to respond to the allegations in Paragraph 39 that set forth legal conclusions. However, to the extent that such allegations may be construed against it, Defendant denies them

and lacks knowledge or information sufficient to form a belief about the truth of the allegations as to the other Defendants.

40. Defendant denies that it manufactured, compounded, sold, tested and/or distributed MPA. Defendant is not required to respond to the allegations in Paragraph 40 that set forth legal conclusions. However, to the extent that such allegations may be construed against it, Defendant denies them and lacks knowledge or information sufficient to form a belief about the truth of the allegations as to the other Defendants.

41. Defendant denies that it designed, manufactured, compounded, tested, warned, marketed and/or sold MPA. Defendant is not required to respond to the allegations in Paragraph 41 that set forth legal conclusions. However, to the extent that such allegations may be construed against it, Defendant denies them and lacks knowledge or information sufficient to form a belief about the truth of the allegations as to the other Defendants.

- a. Defendant denies that it shipped MPA. Defendant is not required to respond to the allegations in Paragraph 41(a) that set forth legal conclusions. However, to the extent that such allegations may be construed against it, Defendant denies them and lacks knowledge or information sufficient to form a belief about the truth of the allegations as to the other Defendants.
- b. Defendant is not required to respond to the allegations in Paragraph 41(b) that set forth legal conclusions. However, to the extent that such allegations may be construed against it, Defendant denies them and lacks knowledge or information sufficient to form a belief about the truth of the allegations as to the other Defendants.
- c. Defendant is not required to respond to the allegations in Paragraph 41(c) that set forth legal conclusions. However, to the extent that such allegations may be construed against it, Defendant denies them and lacks knowledge or information sufficient to form a belief about the truth of the allegations as to the other Defendants.
- d. Defendant is not required to respond to the allegations in Paragraph 41(d) that set forth legal conclusions. However, to the extent that such allegations may be construed against it, Defendant denies them and lacks knowledge or information sufficient to form a belief about the truth of the allegations as to the other Defendants.

- e. Defendant is not required to respond to the allegations in Paragraph 41(e) that set forth legal conclusions. However, to the extent that such allegations may be construed against it, Defendant denies them and lacks knowledge or information sufficient to form a belief about the truth of the allegations as to the other Defendants.
- f. Defendant is not required to respond to the allegations in Paragraph 41(f) that set forth legal conclusions. However, to the extent that such allegations may be construed against it, Defendant denies them and lacks knowledge or information sufficient to form a belief about the truth of the allegations as to the other Defendants.
- g. Defendant denies that it designed, compounded and/or manufactured MPA. Defendant is not required to respond to the allegations in Paragraph 41(g) that set forth legal conclusions. However, to the extent that such allegations may be construed against it, Defendant denies them and lacks knowledge or information sufficient to form a belief about the truth of the allegations as to the other Defendants.
- h. Defendant denies that it tested MPA. Defendant is not required to respond to the allegations in Paragraph 41(h) that set forth legal conclusions. However, to the extent that such allegations may be construed against it, Defendant denies them and lacks knowledge or information sufficient to form a belief about the truth of the allegations as to the other Defendants.
- i. Defendant denies that it compounded MPA. Defendant is not required to respond to the allegations in Paragraph 41(i) that set forth legal conclusions. However, to the extent that such allegations may be construed against it, Defendant denies them and lacks knowledge or information sufficient to form a belief about the truth of the allegations as to the other Defendants.
- j. Defendant denies that it manufactured and compounded MPA. Defendant is not required to respond to the allegations in Paragraph 41(j) that set forth legal conclusions. However, to the extent that such allegations may be construed against it, Defendant denies them and lacks knowledge or information sufficient to form a belief about the truth of the allegations as to the other Defendants.
- k. Defendant is not required to respond to the allegations in Paragraph 41(k) that set forth legal conclusions. However, to the extent that such allegations may be construed against it, Defendant denies them and lacks knowledge or information sufficient to form a belief about the truth of the allegations as to the other Defendants.

42. Defendant is not required to respond to the allegations in Paragraph 42 that set forth legal conclusions. However, to the extent that such allegations may be construed against it, Defendant denies them and lacks knowledge or information sufficient to form a belief about the truth of the allegations as to the other Defendants and Plaintiff's injuries.

43. Defendant is not required to respond to the allegations in Paragraph 43 that set forth legal conclusions. However, to the extent that such allegations may be construed against it, Defendant denies them and lacks knowledge or information sufficient to form a belief about the truth of the allegations as to the other Defendants and Plaintiff's injuries.

RESPONDING TO WHEREFORE CLAUSE

Defendant denies entitlement to the relief requested in the Complaint. Defendant demands a trial by jury.

COUNT III - NEGLIGENCE

44. Defendant repeats and restates the responses of the preceding paragraphs as if fully set forth herein.

45. The allegations in Paragraph 45 are not directed to this Defendant so no response is required. To the extent one is deemed required, Defendant denies the allegations in Paragraph 45 for lack of knowledge or information sufficient to form a belief about the truth of these allegations.

46. The allegations in Paragraph 46 are not directed to this Defendant so no response is required. To the extent one is deemed required, Defendant denies the allegations in Paragraph 46 for lack of knowledge or information sufficient to form a belief about the truth of these allegations.

a. The allegations in Paragraph 46(a) are not directed to this Defendant so no response is required. To the extent one is deemed required, Defendant denies the allegations in

Paragraph 46(a) for lack of knowledge or information sufficient to form a belief about the truth of these allegations.

- b. Defendant denies that it manufactured and/or compounded MPA. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 46(b) as to the other Defendants.

47. The allegations in Paragraph 47 are not directed to this Defendant so no response is required. To the extent one is deemed required, Defendant denies the allegations in Paragraph 47 for lack of knowledge or information sufficient to form a belief about the truth of these allegations.

RESPONDING TO WHEREFORE CLAUSE

Defendant denies entitlement to the relief requested in the Complaint. Defendant demands a trial by jury.

COUNT IV – BREACH OF EXPRESS WARRANTY

48. Defendant repeats and restates the responses of the preceding paragraphs as if fully set forth herein.

49. Defendant denies that it made any warranties or representations regarding MPA. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 49 as to the other Defendants.

50. Defendant denies that it made any warranties or representations regarding MPA. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 50 as to the other Defendants.

51. Defendant is not required to respond to the allegations in Paragraph 51 that set forth legal conclusions. However, to the extent that such allegations may be construed against it,

Defendant denies them and lacks knowledge or information sufficient to form a belief about the truth of the allegations as to the other Defendants and Plaintiff's injuries.

RESPONDING TO WHEREFORE CLAUSE

Defendant denies entitlement to the relief requested in the Complaint. Defendant demands a trial by jury.

COUNT V – LOSS OF CONSORTIUM

52. Defendant repeats and restates the responses of the preceding paragraphs as if fully set forth herein.

53. Defendant lacks knowledge or information sufficient to form a belief about the truth of the allegations in Paragraph 53.

54. Defendant is not required to respond to the allegations in Paragraph 54 that set forth legal conclusions. However, to the extent that such allegations may be construed against it, Defendant denies them and lacks knowledge or information sufficient to form a belief about the truth of the allegations as to the other Defendants and Plaintiff's injuries.

RESPONDING TO WHEREFORE CLAUSE

Defendant denies entitlement to the relief requested in the Complaint. Defendant demands a trial by jury.

DEFENSES AND AFFIRMATIVE DEFENSES

During the course of litigation, a number of defenses and/or affirmative defenses may become available to Defendant. To the extent any of the following are available and may apply, notice is hereby given of the following:

1. The Complaint fails to state a claim or cause of action cognizable in law or equity against Defendant Ameridose.

2. The Complaint fails to allege a cognizable claim for breach of any applicable standard for the practice of pharmacy as to Defendant Ameridose.

3. Plaintiffs lack standing to sue Defendant Ameridose.

4. Defendant did not make the product in question and has no liability here since it is a separate entity not responsible for the acts of the other Defendants.

5. The allegations of the Complaint do not adequately set forth the elements required to overcome the presumption of corporate separateness under applicable state law.

6. The Complaint fails to sufficiently identify a preparation compounded or manufactured by this Defendant.

7. The alleged injuries or damages may have been proximately caused by one or more unforeseeable, independent intervening or superseding events beyond the control of and unrelated to the conduct of Defendant, including Plaintiffs' comparative fault, pre-existing medical condition, and/or idiosyncratic reaction.

8. The Defendant further states that if the Plaintiffs underwent the medical procedure, they did so after having been fully, fairly, and reasonably informed and made aware of risks and uncertainties involved, and that after having been so informed consistent with the informed consent and or incurred risk doctrines of New Jersey, they exercised their informed consent to the performance of the procedure.

9. Adequate warnings and information were available to the medical profession, including any prescribing or administering healthcare provider.

10. Defendant relies upon all applicable defenses afforded it under the New Jersey Products Liability Act of 1987, N.J.S.A. 2A:58C-1, *et seq.*

11. To the extent that Plaintiffs' claims are based on violations of the Federal Food Drug & Cosmetic Act, such claims must fail since there is no private right of action regarding these alleged violations.

12. Plaintiffs' alleged injuries and/or damages, if any, were caused or contributed to by entities other than this Defendant and those named as Defendants in this action. Fault and a percentage of liability must be apportioned to all who caused or contributed to the Plaintiffs' alleged injury under applicable state law.

13. Defendant incorporates and adopts by reference any and all applicable affirmative defenses, raised or to be raised by any other party, and expressly reserves the right to amend and supplement its Answer or to assert additional affirmative defenses at or before trial as additional information is obtained through investigation and discovery.

WHEREFORE, Defendant demands Judgment of this Court:

- a. dismissing the Complaint against it, with prejudice;
- b. awarding to Defendant the costs, expenses, and fees associated with defending this action; and
- c. granting such other and further relief, both legal and equitable, that the Court deems just and proper.

Dated: January 14, 2013

CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 11.2

Pursuant to Local Civil Rule 11.2, I certify under penalty of perjury that the matter in controversy is not subject to any other known action pending in any court or of any pending arbitration of administrative proceeding.

Respectfully submitted,

s/ Walter F. Timpone

Walter F. Timpone

Walter R. Krzastek

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Attorneys for Defendant Ameridose, LLC

CERTIFICATE OF SERVICE

This is to certify that a copy of the foregoing has been filed with the Clerk of the Court on January 14, 2013 using the ECF system that sent notification of this filing to all ECF-registered counsel of record via e-mail generated by the Court's ECF system.

s/ Walter F. Timpone

Attorney for Defendant Ameridose, LLC